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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA, OAKLAND DIVISION

IN RE PLUM BABY FOOD LITIGATION This Document Relates To: All Actions	Master File No. 4:21-cv-00913-YGR Hon: Yvonne Gonzalez Rogers **DEFENDANT PLUM, PBC'S NOTICE OF MOTION AND MOTION TO DISMISS, OR IN THE ALTERNATIVE, TO STAY; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF** Date: January 11, 2022 Time: 2:00 p.m. Courtroom: 1 [*Declaration of Keri E. Borders and [Proposed] Order Filed Concurrently Herewith*]

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on January 11, 2022, at 2:00 p.m., or as soon thereafter as the matter may be heard, in Courtroom 1, 4th Floor, of this Court, located at 1301 Clay Street, Oakland, CA 94612, before the Honorable Yvonne Gonzalez Rogers, defendant Plum, PBC (also erroneously sued as Plum, Inc.[1]) (collectively, "Plum") will and hereby does move the Court for an order dismissing the first amended consolidated class action complaint ("FACC"), and each claim contained therein, with prejudice, or in the alternative, staying this action.

This motion is made pursuant to Fed. R. Civ. P. 8, 12(b)(1), and 12(b)(6), and is based on the following grounds:

1. Plaintiffs lack Article III standing to pursue their claims and to seek injunctive relief;

2. Plaintiffs' state law claims are barred by the doctrine of conflict preemption;

3. The Court should dismiss/stay this case in deference to FDA's primary jurisdiction;

4. Plaintiffs do not plausibly allege that they were, or that reasonable consumers would be, deceived by the challenged statements and omissions in the manner alleged; and

5. Plaintiffs' claims for breach of implied warranty fail for the additional reason that plaintiffs cannot allege that the challenged products were not fit for their ordinary purpose.

The motion is supported by this notice, the attached memorandum of points and authorities, the declaration of Keri E. Borders, pleadings and documents on file in this case, and on such other written and oral argument as may be presented to the Court on this matter motion.

Dated: October 18, 2021

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by: /s/ *Keri E. Borders*
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[1] In 2013, Plum, Inc. was converted into a public benefit corporation and was renamed Plum, PBC. Accordingly, Plum, Inc. no longer exists.

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STATEMENT OF ISSUES TO BE DECIDED

1. Do plaintiffs have Article III standing to pursue their claims?

2. Are plaintiffs' state-law claims preempted?

3. Should plaintiffs' claims be dismissed (or stayed) pursuant to the primary jurisdiction doctrine?

4. Have plaintiffs plausibly alleged that they were deceived by Plum's labels?

5. Have plaintiffs adequately alleged a claim for breach of implied warranty?

I. INTRODUCTION

Because plaintiffs have not alleged a cognizable injury—and separately because this false advertising consumer class action is an implausible and improper attempt to appropriate the mandate of the Food & Drug Administration ("FDA") to develop and implement national food safety and labeling policy—the first amended consolidated complaint ("FACC") should be dismissed or, at a minimum, stayed on numerous independent grounds.

Plaintiffs sue on behalf of a putative class of purchasers of baby food products sold under the "Plum Organics" brand, alleging that they were deceived because Plum labeling did not disclose that low levels of certain heavy metals *may* exist in those products as a result of their ingredients. Plaintiffs' lawsuit follows on the heels of a February 4, 2021 staff report issued by the Subcommittee on Economic and Consumer Policy of the U.S. House of Representatives' Committee regarding heavy metals in baby food (the "Subcommittee Report"). The Subcommittee Report claimed to follow an "investigation" into the presence of naturally occurring trace amounts of heavy metals in the fruits, vegetables and rice in baby food—the same trace heavy metals levels ubiquitous in all such fruits, vegetables and rice in the U.S. food supply—and raised alarm that baby food products sold by virtually all manufacturers might be "unsafe." The immediate fear caused to caretakers was as needless as it was expected. The Subcommittee Report relied heavily on a report previously issued by a consumer advocacy group, whose methods and conclusions have never been peer reviewed or tested. Moreover, the Subcommittee Report was the work product of politicians and their staff, not qualified scientists. Notably, the Subcommittee Report called on FDA—the agency charged with authority to ensure

the safety of the U.S. food supply and to regulate food products—to take specific actions related to testing, labeling, use and non-use of certain ingredients, and the setting of "action levels" (i.e., maximum allowable levels), where necessary, for heavy metals in baby food.

FDA responded quickly to the Subcommittee Report. Rather than endorsing it or the Subcommittee's recommendations, FDA expressed serious concern over politicians making proposals that were not science based and that could harm children by reducing their consumption of healthy and nutritious food. FDA also corrected a significant erroneous implication of the Subcommittee Report, i.e., that FDA had failed to act. FDA *does* actively monitor heavy metals in the food supply. Its decision not to set action levels in the past or engage in other rulemaking to regulate baby food reflects the results of FDA's active monitoring and its considered judgment that such actions were not warranted or necessary. FDA made clear that its "testing [. . .] shows that children are *not at an immediate health risk* from exposure to toxic elements in food." Declaration of Keri E. Borders ("Borders Decl."), Ex. E at 3. With these and other statements, FDA did what it could to reassure the public that packaged baby food has been and remains safe, and should continue to feed babies and toddlers packaged baby food.

Nevertheless, within days of the issuance of the Subcommittee Report, consumer lawyers began filing what are now 136 materially identical consumer class actions against baby food manufacturers alleging that their baby food products were "falsely advertised" because the product labels did not expressly "disclose" the presence of one or more of the heavy metals found in almost all food.

Plaintiffs' claims have no merit. FDA is on the job and has been focusing on the issues addressed in the Subcommittee Report for years. As part of its past work, FDA concluded that setting action levels, such as for arsenic in infant rice cereal, was appropriate[2], but declined to do so for other baby food products. Now, FDA is formally redoubling its efforts and re-considering its work. FDA has made clear that—if deemed necessary by qualified experts reviewing relevant

[2] FDA also issued guidance regarding acceptable limits for lead in candy. *See* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children. .

evidence, and after hearing from all stakeholders—it may adopt regulations, including action levels, regarding heavy metals in food. Consistent with its mandate, FDA will ensure that any such action will be supported by the scientific evidence. Claims in private litigation seeking to impose remedies that necessarily differ from FDA's considered judgment—on a piecemeal case-by-case, company-by-company, product-by-product basis, no less—are barred by conflict preemption. Separately, where, as here, FDA is currently and formally continuing its review of these issues and has previewed that it will determine based on such review whether rulemaking is warranted, lawsuits overlapping with FDA's work should be dismissed (or, at a minimum, stayed) in deference to FDA's primary jurisdiction.

But the Court need not reach those dispositive arguments because the FACC fails at the outset to allege an injury in fact, a threshold fundamental allegation required to demonstrate Article III standing, as recently confirmed in this Circuit and elsewhere. Plaintiffs' allegations that their purchased products *may* have contained *some* heavy metals, with no specific allegations of how these plaintiffs were, or could have been, *actually injured*, is insufficient to allege standing. Additionally, the FACC fails to state a claim because plaintiffs do not plausibly allege that they were deceived by the labeling or advertising of Plum's baby food products, plaintiffs lack standing to assert claims for injunctive relief, and plaintiffs fail to state a claim for breach of implied warranty.

For these reasons, as set forth more fully below, the motion to dismiss the FACC should be granted.

II. FACTUAL BACKGROUND

A. FDA Is Responsible For Regulating Food Safety, Including Heavy Metals, In The U.S. Food Supply

The Food Drug & Cosmetic Act ("FDCA") requires FDA to (i) ensure that foods are safe, wholesome, sanitary, and properly labeled, (ii) promulgate regulations to enforce the provisions of the FDCA, and (iii) enforce its regulations through administrative proceedings. 21 U.S.C. §§ 371, 393(b)(2)(A), 21 C.F.R. §§ 7.1, *et seq*.

The FDCA prohibits "[t]he introduction or delivery for introduction into interstate

commerce of any food . . . that is adulterated[.]" 21 U.S.C. §§ 331(a). Food is deemed to be adulterated when it fails to meet certain standards, including when it is harmful to human health. *See* 21 U.S.C. § 342. Relevant here, a food is not deemed to be adulterated because of the presence of unavoidable heavy metals or any other substance "*if the quantity of such substance in such food does not ordinarily render it injurious to health.*" 21 U.S.C. § 342 (emphasis added). Further, federal law requires that when such a substance cannot be avoided in food and may be present at levels that could be harmful, FDA sets action levels that may not be exceeded. 21 U.S.C. § 346. The action levels reflect considered scientific judgment and decision-making about when food may be rendered unsafe by the presence of poisonous or deleterious substances.

All of this means that when a food contains harmful substances such that it is deemed adulterated under the law and unsafe to consume, the food is prohibited to be sold in interstate commerce. Following from this, FDA is and has been for decades well aware of heavy metals in the U.S. food supply and has been taking action it deems warranted and appropriate under the law, and declining to take action where action is unnecessary or unwarranted under the law.[3]

Thus, where an allegedly poisonous or deleterious substance is in food and cannot be avoided entirely, FDA sets limits for the contaminant that may not be exceeded. FDA has not found it warranted or necessary to set a limit for most heavy metals in baby food. Significantly, that is because FDA limits substances when it determines that the substances may be present in harmful or dangerous levels and FDA has not made that determination. Moreover, if it is determined that food is adulterated within the meaning of Section 342, FDA has the authority to order a recall of that food. 21 U.S.C. § 350l. FDA confirms this in its February 16, 2021 Constituent Update, when it states that if FDA finds that the products violate the law, including

[3] If plaintiffs' argument is that FDA is not following the law or meeting its obligations (and there is zero support in the FACC for that assertion), that challenge is properly brought in a citizen's petition or a lawsuit directed at the agency itself. *See* 21 C.F.R. § 10.30; *Takeda Pharms. U.S.A., Inc. v. Burwell*, 691 F. App'x 634, 636 (D.C. Cir. 2016); *Arent v. Shalala*, 70 F.3d 610, 612 (D.C. Cir. 1995); *All. for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 170 (D.D.C. 2000). Permitting plaintiffs to use the consumer class action device against food manufacturers to raise grievances that, at best for plaintiffs, should be directed to FDA threatens to upend the orderly and uniform national standard for food regulation. It would also lead to the untenable scenario of companies being held liable for following FDA regulations and guidance.

not being safe, "the agency takes steps to stop the product from being imported, takes court action to stop its sale or recalls it if it is in the domestic market." Borders Decl., Ex. C at 2. Again, with respect to baby food, and in direct response to the Subcommittee Report, FDA informed the public that "testing shows that children are *not at an immediate health risk* from exposure to toxic elements in foods." Borders Decl., Ex. E at 3. FDA also assured the public that it "routinely monitors" levels of heavy metals, and if the levels pose a health risk, FDA would take steps to remove the affected foods from the market. *Id*. FDA urged consumers not to throw out or stop feeding packaged baby foods to babies and children, cautioning that eliminating food groups from children's diets could result in nutritional deficiencies and potential poor health outcomes. *See id*. In doing so, FDA recognized that given the ubiquitous nature of heavy metals, there are limits to how low the levels in food can be, and requiring levels that are neither justified nor feasible "could result in significant reductions in the availability of nutritious, affordable foods that many families rely on for their children." Borders Decl., Ex. J at 1.

B. FDA's "Closer To Zero: Action Plan For Baby Foods"

On April 8, 2021—in direct response to the Subcommittee Report—FDA announced its "Closer to Zero: Action Plan for Baby Foods," a comprehensive multi-year plan identifying actions FDA "will take to reduce exposure to toxic elements from foods eaten by babies and young children—to as low as possible." Borders Decl., Ex. B at 1. Significantly, the Action Plan recognizes that "[r]educing levels of toxic elements in foods is complicated and multifaceted," and that it is "crucial" that measures taken not have unintended harmful consequences such as eliminating from the marketplace certain foods, committing itself to a "science-driven, transparent, and inclusive process that will include active stakeholder engagement and public sharing of data and information." *Id*. at 2.

The Action Plan has four specific stages: (1) evaluating the scientific basis for action levels, including establishing an interim reference level for certain toxic elements as appropriate; (2) proposing action levels for certain elements in categories of baby foods and other foods

commonly eaten by babies and young children; (3) consulting with stakeholders regarding proposed action levels; and (4) finalizing those levels. *Id*. at 3-4.[4]

Beginning in April 2021, FDA proposed a specific timeline for the four phases, and will "establish a timeframe for assessing industry's progress toward meeting the action levels and recommence the cycle to determine if the scientific data supports efforts to further adjust the action levels." *Id*. at 4. On October 8, 2021, FDA formally announced its first public meeting to receive stakeholder input on its Action Plan. Borders Decl., Ex. F.

Contrary to a specific remedy plaintiffs seek in this action, the Action Plan does not contemplate requiring warning labels or disclosures on baby food products regarding ubiquitous heavy metals in the food supply, and there is no basis to assume, let alone conclude, that the final policy decisions implemented by FDA will require manufacturers to change their labeling or advertising in any way. Regardless, like the action level determinations, labeling requirements, too, would be FDA's decision to make.

III. ARGUMENT

A. Plaintiffs Lack Standing To Pursue Their Claims

1. Plaintiffs Have Not Pleaded That They Suffered An Injury In Fact

As a threshold dispositive matter, plaintiffs fail to allege that they suffered an injury in fact and, thus, they lack Article III standing. Specifically, plaintiffs have not (and cannot) allege that they suffered a physical or economic injury as a result of their past purchases of safe to consume baby food. To establish Article III standing, a plaintiff must show that "(1) he or she has suffered an injury in fact that is concrete and particularized, and actual or imminent; (2) the injury is fairly traceable to the challenged conduct; and (3) the injury is likely to be redressed by a favorable court decision." *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1225 (9th Cir. 2008); *McGee v. S-L Snacks Nat'l*, 982 F.3d 700, 706 (9th Cir. 2020).

[4] FDA defines "[a]ction levels a[s] a level of contamination at which a food may be regarded as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act." Borders Decl., Ex. E at 2.

Allegations of actual injury suffered by plaintiffs are nonexistent in the FACC. That makes sense given that (i) plaintiffs and their children suffered no physical injury; and (ii) plaintiffs purchased and received baby food products that their children presumably consumed. And that, in turn, makes sense given that FDA has made clear, subsequent to the Subcommittee Report, that packaged baby food is safe and consumers should *not* throw out or cease feeding their children packaged baby food. Borders Decl., Ex. D at 2.

What the FACC *does* allege is that plaintiffs would not have purchased Plum products[5] if they had been aware of the presence, or risk of the presence, of heavy metals in baby food. *See* FACC ¶¶ 30, 33, 36, 39, 42, 45, 48, 51, 53, 56. Plaintiffs allege that they paid money for products that were tainted by the mere presence of heavy metals and that because of that the products were completely worthless and plaintiffs are entitled to a refund of the entire purchase price.[6] *See e.g.*, FACC ¶ 239 (plaintiffs seek restitution "in the amount they spent on the Baby Foods"); 323 (plaintiffs seek injunctive and declaratory relief, full refund, actual and punitive damages, statutory damages, and attorneys' fees). But as a robust body of case law clearly holds, these allegations of hypothetical economic injury do not constitute a legally cognizable injury that confers standing, where, like here, the products were not "worthless."

[5] Presumably, on this same logic, plaintiffs would not have purchased any foods containing vegetables, fruits or grains *at all*, considering all foods grown in soil, water and air may contain some amount of heavy metals from the environment.

[6] Plaintiffs fail to allege that the specific baby food products *they* purchased contained any of the alleged contaminants, which provides another basis to dismiss the FACC. *See, e.g.*, *Gaminde v. Lang Pharma Nutrition, Inc.*, 2019 WL 1338724 (N.D.N.Y. Mar. 25, 2019) (dismissing putative action for lack of standing where there was no showing that *plaintiff* had tested the particular product *he* purchased); *In re Apple Processor Litig.*, 2019 WL 3533876, at *8 (N.D. Cal. Aug. 2, 2019). Instead, plaintiffs rely on testing discussed in the Subcommittee Report conducted by third-party Healthy Babies Bright Futures for the allegation that "limited independent testing has revealed the presence of toxic heavy metals in [Plum's] baby food," FACC, Ex. 1 at 45, and "recent testing" of two Plum products, *id.* ¶ 19. However, these third-party sources have no bearing on the baby food *plaintiffs* purchased, and plaintiffs cannot save their claims with equivocal language that the baby food *could* have contained alleged contaminants. Moreover, the Subcommittee Report does not claim that all of the products discussed therein contained all of the challenged heavy metals at levels of concern. *See generally* FACC, Ex. 1. Rather, the Subcommittee Report asserts that some products may contain certain alleged contaminants at levels of concern, at the date of testing. *Id.*

For example, in *Herrington v. Johnson & Johnson Consumer Companies*, 2010 WL 3448531 (N.D. Cal. Sept. 1, 2010), plaintiffs argued that they pleaded an injury sufficient to confer standing because "they unknowingly purchased products containing potential carcinogens and that 'they would have never purchased these products had they known of the presence of these contaminants.'" *Id*. at *4. The court rejected the theory on an Article III basis, reasoning that plaintiffs failed to plead "a distinct risk of harm from a defect in Defendants' products that would make such an economic injury cognizable." *Id*. Specifically, plaintiffs failed to plead that the challenged products were unfit for use or defective, and allegations that carcinogens had been detected in the bath products, that scientists believed there is no safe level of exposure to a carcinogen, and that children are generally more vulnerable to toxic exposure than adults were *not* sufficient to show a palpable risk. *Id*. at *3 ("[plaintiffs] only allege that 1,4–dioxane and formaldehyde *may* be carcinogenic for humans, that there *could* be no safe levels for exposure to carcinogens and that Defendants' products contain some amount of these substances.").

Plaintiffs' allegations are no better than those rejected in *Herrington*. Plaintiffs do not allege (because they can't) that any of the baby food products they purchased contained levels of heavy metals that rendered them unsafe to consume or devoid of nutrition and were, therefore, worthless. That tracks with the FDA's clear pronouncements repeated in this motion: these products are not harmful, are safe to consume, and parents and caregivers should continue to serve them. *See Allen v. Hyland's Inc.*, 300 F.R.D. 643, 671 n.25 (C.D. Cal. 2014) (food products have inherent nutritional value and, thus, are not worthless); *Brazil v. Dole Packaged Foods LLC*, 660 F. App'x 531, 534 (9th Cir. 2016) (full refund model inappropriate because some benefits were conferred); *In re Tobacco Cases II*, 240 Cal. App. 4th 779, 802 (2015) (full refund damages only proper where product confers no benefit on consumers); *In re Pom Wonderful LLC*, 2014 WL 1225184, at *3 (C.D. Cal. Mar. 25, 2014) (because plaintiffs received some benefit from the product (regardless of the benefits they sought) a full refund was inappropriate).

Nor can plaintiffs plausibly allege that they did not receive the benefit of the bargain of their purchase as courts in California and elsewhere have routinely rejected the claim that trace amounts of substances (including heavy metals) in consumer products negate the value of the

consumer's purchase. In *Boysen v. Walgreen Co.*, 2012 WL 2953069, at *4 (N.D. Cal. July 19, 2012), the court found that plaintiffs lacked standing to bring a claim against a company for failure to disclose that its juice product contained lead. *Id.* at *1, 7. The plaintiffs admitted that the levels of lead in the juice were below FDA limits and that no plaintiff alleged physical harm. *Id.* at *1-2. Instead, plaintiffs argued that they had been injured in fact because they would not have bought the juice if they had known it contained any amount of lead. *Id.* The court rejected this theory of injury because, without any allegation that the juice tended to cause actual physical harm, plaintiffs had received the benefit of the bargain and thus had not alleged how purchasing the juice had injured them. *Id.* at *7; *see also Koronthaly v. L'Oreal USA, Inc.*, 2008 WL 2938045, at *4-5 (D.N.J. July 29, 2008), *aff'd*, 374 F. App'x 257 (3d Cir. 2010) (plaintiff lacked standing to bring suit against lipstick manufacturer where trace amounts of lead in lipstick did not exceed FDA standards); *Moreno v. Vi-Jon, Inc.*, 2021 WL 807683 (S.D. Cal. March 3, 2021) (no injury where plaintiff did not allege that he purchased or used hand sanitizer to prevent any of the diseases or viruses the hand sanitizer purportedly failed to protect against, or that he contracted any of those diseases or viruses); *Doss v. Gen. Mills, Inc.*, 816 F. App'x 312, 314 (11th Cir. 2020) (no economic injury because where plaintiffs alleged "ultra-low levels of glyphosate . . . may be harmful to human health"); *Green v. PepsiCo, Inc.*, 2019 WL 8810364, at *1, 3 (S.D. Fla. Apr. 12, 2019) (dismissing case because plaintiff failed to allege an injury in fact based on her purchase of Quaker Oats that allegedly contained trace amounts of residual glyphosate); *see also McGee*, 982 F.3d at 706 (plaintiff's assumption that food product containing trans fat contained only safe and healthy ingredients was not part of the bargain).

Nor can plaintiffs allege that they satisfy Article III based on a theory that they paid a price premium given that, according to the FACC, *all* baby food potentially contains trace amounts of heavy metals, making the presence of heavy metals irrelevant to pricing. FDA also confirms this point when it states that the alleged contaminants are omnipresent in the environment, and are inescapable, including for parents who opt to make their own foods.[7]

[7] Plaintiffs' assertion that several baby food products have paid to receive an endorsement from a for-profit third-party (the Clean Label Project's Purity Award) does not help them for several

Plaintiffs also confirm as much when they seek (in the prayer for relief) restitution of the *total* purchase price, not a price premium.

Plaintiffs cannot and do not allege they have been harmed by any of the products they purchased. The mere *possibility* that *some* products contained *some* levels of heavy metals which *could* cause harm under *certain* circumstances is, as a matter of law, insufficient to confer Article III standing.

2. Plaintiffs Lack Standing To Seek Injunctive Relief

Plaintiffs also lack Article III standing to pursue injunctive relief because they do not make the required allegation of a likelihood of suffering imminent and irreparable injury in the future without an injunction. *Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 966-72 (9th Cir. 2018); *see also Stover v. Experian Holdings, Inc.*, 978 F.3d 1082, 1087 (9th Cir. 2020) (*Davidson* requires a plaintiff to plausibly allege a desire to purchase the product in the future). Plaintiffs must demonstrate "a sufficient likelihood that [they] will *again* be wronged in a *similar* way," but they fail to make those allegations. *City of L.A. v. Lyons*, 461 U.S. 95, 111 (1983) (emphasis added).

As the FACC readily and repeatedly acknowledges, plaintiffs are now fully aware that heavy metals are ubiquitous in the environment and that it is not possible to eliminate heavy metals in the food supply, including specifically in packaged baby food. Nevertheless, plaintiffs allege that they would be willing to purchase the products again in the future if they could be certain that they "do not contain heavy metals." FACC ¶¶ 30, 33, 36, 39, 42, 45, 48, 51, 53, 56. But that doesn't work. Plaintiffs are conclusively aware of the pervasiveness of heavy metals and cannot ignore the avalanche of allegations in the FACC making that crystal clear. "[W]here a

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reasons, including that per plaintiffs' allegations, the Clean Label Project "presents its Purity Award to companies with products with the *lowest* [not zero] levels of the contaminants when compared to other products in a given category." FACC ¶ 150 (emphasis added). This does not mean that products endorsed by the Clean Label Project (for a fee) are free from, or have no material risk of containing, the alleged contaminants, and thus, according to plaintiffs' own theory the products would still be deceptively marketed and sold. It is also worth noting that the award is not focused solely on measurement of the substances challenged in the FACC, but includes an analysis of other substances such as pesticide residues and plasticizers. *See* https://cleanlabelproject.org/purity-award/methodology/.

plaintiff learns information during litigation that enables her to evaluate product claims and make appropriate purchasing decisions going forward, an injunction would serve no meaningful purpose as to that plaintiff." *Jackson v. Gen. Mills, Inc.*, 2020 WL 5106652, at *5 (S.D. Cal. Aug. 28, 2020).

Moreover, plaintiffs' assertion they "may" purchase the products again in the future if they could be certain that they do not contain heavy metals is too vague and uncertain to establish a likelihood of imminent harm. Plaintiffs do not allege that they are in a position to buy baby food again (e.g., that they are caretakers for infants or young children today or that someone in their household eats baby food), much less that that they have a concrete plan to purchase baby food and would be harmed without a disclaimer of facts they already know. *See Lanovaz v. Twinings N. Am., Inc.*, 726 F. App'x 590, 591 (9th Cir. 2018) (holding that the plaintiffs "would 'consider buying'" allegations insufficient because profession of a "some day" intention does not support a finding of actual or imminent injury (quotation marks and citation omitted)); *Joslin v. Clif Bar & Co.*, 2019 WL 5690632, at *4 (N.D. Cal. Aug. 26, 2019) (no actual or imminent injury where plaintiffs alleged defendant's product did not contain real white chocolate and they "do not want products that do not contain real white chocolate").

Accordingly, plaintiffs cannot establish a likelihood of future harm sufficient to confer standing to sue for injunctive relief because the requested disclaimer of the potential presence of heavy metals in food would serve no purpose for them. *See Cimoli v. Alacer Corp.*, --- F. Supp. 3d ----, 2021 WL 2711770, at *7 (N.D. Cal. July 1, 2021); *Rahman v. Mott's LLP*, 2018 WL 4585024, at *3 (N.D. Cal. Sept. 25, 2018).

B. Plaintiffs' Claims Should Be Dismissed As Preempted

Separate from a failure of Article III standing, plaintiffs' claims are preempted as conflicting with FDA's considered judgment about the safety and labeling of baby food. Plaintiffs' claims—and the underlying relief sought (mandatory food labeling or injunctions prohibiting the sale of baby food)—directly conflict with FDA's role under federal law to establish a uniform, national policy for food safety, including regulation of heavy metals in the food supply. Under the Supremacy Clause, conflicts that arise between state and federal law

must, of course, be resolved in favor of federal law. *See* U.S. CONST. art. VI, cl. 2 ("[T]he Laws of the United States . . . shall be the supreme Law of the Land"); *Maryland v. Louisiana*, 451 U.S. 725, 746-47 (1981). Conflict preemption applies where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Ting v. AT&T*, 319 F.3d 1126, 1136 (9th Cir. 2003) (internal quotation marks and citations omitted). Obstacle preemption applies when the Court can "infer that Congress made 'a considered judgment' or 'a deliberate choice' to preclude state regulation when a federal enactment clearly struck a particular balance of interests that would be disturbed or impeded by state regulation." *Cohen v. Apple, Inc.* 497 F. Supp. 3d 769 (N.D. Cal. 2020) (citing *Arizona v. United States*, 567, U.S. 387, 405 (2012) (imposing criminal penalties on aliens who sought unlawful employment would interfere with Congress' judgment not to impose such penalties).

Significantly, where a federal regulatory agency like FDA has regulated in an area of its expertise pursuant to a legal mandate, state law may not be used to bar conduct the agency has chosen to not prohibit. Otherwise, the threat of civil liability would erect an obstacle to the accomplishment of the comprehensive and carefully calibrated federal regulatory program. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881-82 (2000) (federal law that required a percentage of new cars to employ passive-restraint systems impliedly preempted state tort claims that would have had effect of requiring auto manufacturers to install air bags in all new cars); *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 156 (1982) (conflict preemption where state law limited availability of an option that federal agency thought appropriate to ensure its overall regulatory objectives); *Backus v. Nestlé USA, Inc.*, 167 F. Supp. 3d 1068, 1071 (N.D. Cal. 2016) (tort suit imposing liability for presence of ingredient in food would impose liability for something federal law permitted); *Cohen*, 497 F. Supp. at 785-86 (conflict preemption where state law claims could establish testing requirements and standards that conflicted with the uniform standards and testing established by the FCC). Attempts to commandeer FDA's role to regulate food safety and food labeling under the guise of state consumer protection law, as plaintiffs attempt here, are preempted because they conflict with federal law and supremacy.

Farina v. Nokia Inc., 625 F.3d 97 (3d Cir. 2010), is instructive. Relevant to that case, the Federal Communications Commission ("FCC") issued regulations that set limits for radiofrequency ("RF") radiation from phones (the "SAR Guidelines"). *Id.* at 107. Plaintiff filed a lawsuit against Nokia asserting claims for personal injury due to RF radiation that was SAR Guidelines-compliant, asserting that the sale of cell phones that emitted such RF radiation violated *state* law, even though in compliance with the FCC regulations. *Id*. at 105, 107-8. The Third Circuit found that "although [plaintiff] disavows any challenge to the FCC's RF standards . . . , to succeed, *he necessarily must establish that cell phones abiding by the FCC's SAR guidelines are unsafe to operate without a headset*. In other words, [plaintiff] must show that these standards are inadequate—that they are insufficiently protective of public health and safety." *Id*. at 122 (emphasis added). But the court held that "[a]s an agency engaged in rulemaking, the FCC is well positioned to solicit expert opinions and marshal the scientific data to ensure its standards both protect the public and provide for an efficient wireless network. Allowing juries to perform their own risk-utility analysis and second-guess the FCC's conclusion would disrupt the expert balancing underlying the federal scheme." *Id*. at 126. The court also sought to avoid "state-law standards [that] could vary from state to state, eradicating the uniformity necessary to regulating the wireless network." *Id*. On this record, the Third Circuit found that plaintiff's claims were barred by conflict preemption. *Id*. at 133-34

Conflict preemption applies here for the same reasons. FDA pervasively regulates food safety under a grant from Congress. FDA—singularly positioned to solicit expert opinions, marshal the scientific data and harmonize stakeholder interests—has looked at and continues to study the issues of heavy metals in foods and to regulate their presence in the food supply. Contrary to plaintiffs' demand in this lawsuit, FDA—as part of its historical study of heavy metals—has *not* banned their presence in food entirely or found that baby food, much less any of the products challenged in the lawsuit, is adulterated and cannot be sold. Nor, as part of its renewed look at these same issues, has FDA provided any indication that action levels for heavy metals, if adopted at all, will be set at 0, and it has not required any heavy metals labeling. Instead, FDA has decided to take a holistic approach that balances several competing objectives,

and will set action levels as necessary to maintain the safety of the food supply. *See generally* Borders Decl., Ex. B. This is in accord with FDA's historical approach, such as when FDA set action levels for inorganic arsenic in rice cereals for infants, or allowable levels of inorganic substances, including arsenic, cadmium, lead, and mercury, in bottled water. *See* Borders Decl., Ex. I; 21 C.F.R. § 165.110.

The same is true with plaintiffs' request for label warnings or disclosures regarding the presence of heavy metals. FDA is well aware of ubiquitous heavy metals, and has studied their impact on food safety. The presence of heavy metals (and other unavoidable substances in food) was specifically contemplated by the FDCA, which empowers FDA to set action levels and to regulate adulterants to ensure food safety. 21 U.S.C. §§ 342, 346. Both Congress through the FDCA, and FDA "in their deliberate judgment" and per their "deliberate choice" have not required warning labels or disclosures about the presence of ubiquitous heavy metals on any food, including baby food. In fact, in other contexts where it was suggested that FDA require warnings to declare the presence of certain ingredients and substances, FDA has stated that it is "unwilling to require a warning statement in the absence of clear evidence of a hazard. If the agency were to require warnings for ingredients that only cause mild idiosyncratic responses, it is concerned that it would overexpose consumers to warnings. As a result, consumers may ignore, and become inattentive to, all such statements." Food Labeling; Declaration of Ingredients, 56 Fed. Reg. 28592-01, 28615 (Jun. 21, 1991). That concern is applicable here because every food product would need to carry a disclaimer about the potential presence of heavy metals, which would provide no benefit to consumers. Instead, FDA has made clear in the Action Plan that it will address heavy metals in baby food by setting action levels if deemed necessary and by working to reduce heavy metals in the food supply—not by requiring warning labels or disclosures on baby food products.

Permitting plaintiffs and their counsel to act as FDA, under the guise of state law, to set their own requirements and ban trace amounts (or the risk) of contaminants altogether or to find, retroactively, that Plum baby food products should not have been sold or should have a warning label, would "disrupt the expert balancing underlying the federal scheme." *Farina*, 625 F. 3d at

126. A determination of what requirements, if any, should be mandated, and the action levels, if any, that should be set, is squarely for FDA to make. Otherwise, patchwork, contradicting court orders in different cases across the country would make it impossible for companies to comply. Accordingly, the conflict preemption doctrine requires dismissal of the FACC.

C. Plaintiffs' Claims Fall Under FDA's Primary Jurisdiction

At an absolute minimum, the case should be dismissed (or stayed) because its subject matter—the regulation of heavy metals and other contaminants in the U.S. supply of baby food—is to be left to the consideration, judgment, and determinations of FDA, the federal agency with jurisdiction over these issues, with the expertise and resources to handle them properly, and with an open formal docket to engage in rulemaking over them. Significantly, plaintiffs' claims raise numerous food regulatory issues that under the law require resolution by FDA, including the safety of baby food, permitted action levels of heavy metals, what testing and manufacturing processes should be required by manufacturers, and the proper labeling of baby food. *See generally* FACC; *see also Backus v. Gen. Mills, Inc.*, 122 F. Supp. 3d 909, 933–35 (N.D. Cal. 2015). Indeed, plaintiffs specifically ask the Court to enjoin Plum from selling baby food that contains any level of heavy metals and/or unless full disclosure of the presence of heavy metals appears on the label. FACC, Prayer for Relief. These issues require a carefully calibrated national approach to food safety and labeling based on science and only after input from all stakeholders. These issues should not be decided in the first instance by the courts, in a consumer class action no less.

"Primary jurisdiction is a prudential doctrine that permits courts to determine 'that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch.'" *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 760 (9th Cir. 2015) (citation omitted). "The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir.2008). The doctrine applies where, as here, "if a claim 'requires resolution of an issue of

first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency" and when "protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Reese v. Odwalla, Inc.*, 30 F. Supp. 3d 935, 940 (N.D. Cal. 2014).

Courts consider four factors in determining whether to apply the primary jurisdiction doctrine: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek Semiconductor Co. v. Microchip Tech.*, 307 F.3d 775, 781 (9th Cir. 2002) (amended); *accord Astiana*, 783 F.3d at 760. Applying these factors, numerous courts have stayed or dismissed false advertising cases where the underlying theory of deception is incompatible with FDA's primary jurisdiction. *See, e.g.*, *Backus v. Gen. Mills, Inc.*, 122 F. Supp. 3d at 933–35; *Glass v. Glob. Widget, LLC*, 2020 WL 3174688, at *2 (E.D. Cal. June 15, 2020); *Colette v. CV Scis., Inc.*, 2020 WL 2739861, at *1 (C.D. Cal. May 22, 2020); *Tran v. Sioux Honey Ass'n*, 2017 WL 5587276, at *2 (C.D. Cal. Oct. 11, 2017); *Kane v. Chobani, LLC*, 645 F. App'x 593, 594-95 (9th Cir. 2016).

Here, the *Syntek* factors are met because the regulation of heavy metals in food is an issue that Congress has placed within the jurisdiction of FDA because issues surrounding establishment of standards for food safety and labeling require uniformity in administration.

*Firs*t, issues concerning the safety of baby food, permitted action levels of heavy metals, what testing and manufacturing processes should be required, and the proper labeling of baby food fall squarely within the heart of FDA's jurisdiction and mission. FDA is working to promulgate regulations and/or formal guidance resolving FDA's view on these issues, which will be dispositive of the issues raised in the FACC. Indeed, if plaintiffs seek to impose additional or different requirements on Plum, their claims will almost assuredly be expressly preempted. *See* 21 U.S.C. § 343-1. At the very least, FDA's rulemaking and/or final guidance will be highly relevant to Plum's compliance with law. *See, e.g., Rosillo v. Annie's Homegrown Inc.*, 2017 WL 5256345, at *3 (N.D. Cal. Oct. 17, 2017) (FDA guidance regarding the term "natural" is relevant

to a question of how a reasonable consumer would understand that term); *In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 696 (S.D.N.Y. 2016) (similar).

Next, there is no question that "the FDCA subjects the food industry to comprehensive regulation." *Backus v. Gen. Mills*, 122 F. Supp. 3d at 934. "Specifically, the FDCA requires the FDA to (i) ensure that 'foods are safe, wholesome, sanitary, and properly labeled,' (ii) promulgate regulations to enforce the provisions of the FDCA, and (iii) enforce its regulations through administrative proceedings." *Hawkins v. Advancepierre Foods, Inc.*, 2016 WL 6611099, at *3 (S.D. Cal. Nov. 8, 2016), *aff'd*, 733 F. App'x 906 (9th Cir. 2018). This includes vesting FDA with authority to promulgate standards of food quality, and to address the issues raised by this case, including through setting action levels for poisonous substances in food. 21 U.S.C. §§ 341, 346. Moreover, and as this Court recognized in *Reese*, food labeling is an issue over which Congress vested the FDA with comprehensive regulatory authority. 30 F. Supp. 3d at 941. It is thus no surprise that FDA fully recognized its formal role on the issues implicated by the complaint, confirming that it "has been actively working on this issue using a risk-based approach to prioritize and target the agency's efforts." Borders Decl., Ex. C at 1.

Finally, in its Action Plan, FDA is formally and currently working to determine how best to address trace amounts of heavy metals in baby foods and to set additional action levels, as needed. *Reese*, 30 F. Supp. 3d at 941 ("This determination is a matter that is not only within the expertise and authority of the agency, it is before the agency at this moment."). Unless and until FDA completes its work, the Court will not have a clear indication as to how FDA views baby food safety and labeling, and what other factors FDA will set for industry compliance, such as compliance periods or safe harbors.

It is particularly important to permit FDA to apply its expertise in the first instance because the "process of reducing levels of toxic elements in foods is complicated and multifaceted." Borders Decl., Ex. D at 3. As just one example, "[i]t is crucial to ensure that measures to limit toxic elements in foods do not have unintended consequences—like eliminating foods with significant nutritional benefits or reducing the presence of one toxic element while increasing another." *Id*. Moreover, the alleged contaminants "are present in the

environment and may enter the food supply through soil, water or air . . . currently they cannot be completely avoided in the fruits, vegetables, or grains that are the basis for baby foods . . . made by companies or by consumers who make their own foods." Borders Decl., Ex. C at 1. FDA is uniquely capable of taking into consideration food safety, the adequacy of the food supply, and the fact that alleged contaminants are omnipresent in the environment, and reducing all of that to feasible and achievable regulations and/or formal guidance. Borders Decl., Ex. E at 2 ("By taking into consideration issues related to feasibility and achievability, the FDA can help to ensure equitable availability of safe and nutritious foods for all babies and young children."). "FDA has been actively working on this issue using a risk-based approach to prioritize and target the agency's efforts." Borders Decl., Ex. C at 1. Where, as here, the issues posed by a case implicate technical and policy considerations that should be addressed by FDA in the first instance, courts should defer to FDA's primary jurisdiction. *See Clark*, 523 F.3d at 1114--16 (applying primary jurisdiction doctrine where plaintiff's claim "implicat[ed] technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch").

FDA is uniquely situated to draw on vast resources and scientific data to resolve the questions raised by the FACC. FDA has confirmed that it will "work with federal partners, academia, and other stakeholders to inform the development of action levels of lead, cadmium, mercury, and arsenic in foods for babies and young children." Borders Decl., Ex. D at 3. Moreover, it will utilize an "iterative science-based approach for continual improvement and the timeframe for completing action items in three phases." Borders Decl., Ex. E at 2. FDA can draw resources and pull data and information from various sources to which the Court and jurors do not have access.

This all precisely fits with the courts' recognition that "[w]hether a body of evidence sufficiently demonstrates that a particular amount of a chemical substance poses a serious public health risk is precisely the kind of expert question that agencies are better suited to answer than courts or juries." *Backus v. Gen. Mills*, 122 F. Supp. 3d at 934; *see also Tran*, 2017 WL 5587276, at *2 ("These assertions indicate that Tran's contention that she was misled depends on

the harmful nature of glyphosate. Moreover, it is undisputed that no tolerance level has been set for glyphosate in honey and no labeling requirement exists with respect to glyphosate in honey either. The Court is thus unable to conclude whether the 'Pure' and '100% Pure' labeling was misleading without guidance from the FDA on glyphosate's toxicity.").

Permitting courts to act prior to FDA completing its work on the Action Plan won't just seriously disrupt the regulatory process and invade FDA's jurisdiction, but it will also destroy national uniformity. Decisions issuing from the scores of putative class action lawsuits pending against baby food manufacturers in districts across the country will inevitably result in an unworkable patchwork of determinations regarding food safety and labeling requirements that vary by Court, by manufacturer and by product. Plum, for example, could be subjected to completely different requirements by this Court as opposed to the Court in New Jersey. Plum could also be subjected to different requirements from other baby food manufacturers based on decisions in their respective courts. That would also result in different labeling and standards between baby food products, Gerber subject to different standards from Plum, and both different from Beech-Nut. Thus, dismissing or "staying this action until the FDA offers guidance at the federal level would almost certainly help harmonize court rulings—an important consideration in view of the fact that 'Congress [did] not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide" to avoid the need for '[m]anufacturers . . . to print 50 different labels.'" *In re KIND*, 209 F. Supp. 3d at 696 (citation omitted).

D. Plaintiffs Fail To Plausibly Allege Deception

"Heavy metals are naturally occurring in soil and water," and so "[f]ood crops," including crops like carrots and sweet potatoes used by Plum in the manufacture of its baby food products, "uptake these metals naturally." Borders Decl., Ex. A at 2. The levels of these elements in foods depend on many factors, including the levels in the air, water, and soil used to grow the crops, and the type of crop and how much uptake there is from the environment. Borders Decl., Ex. B at 1-2. "Because these elements occur in the environment, currently they cannot be completely avoided in the fruits, vegetables, or grains that are the basis for baby foods, juices,

and infant cereals made by companies or by consumers who make their own foods." Borders Decl. Ex. C at 1. "They also cannot be completely avoided by using organic farming practices." *Id*. Accordingly, "parents can't shop their way out of these exposures by choosing organic foods or by switching from store-bought brands to homemade purees." Borders Decl. Ex. A at 2.

The foundation of plaintiffs' false advertising claims is the allegation that Plum "misleadingly" failed to disclose that "[h]eavy [m]etals, perchlorate, and/or other undesirable toxins or containments" may be present (or that there is a material risk that they may be present) in Plum's baby food. *See, e.g.*, FACC ¶ 11; 165-184. Plaintiffs allege they would not have purchased Plum's baby food (or, assumedly, any baby food) if they had known that heavy metals were present or potentially present in baby food as a result of ingredients like water, rice, sweet potatoes or carrots. *Id.* ¶¶ 30, 33, 36, 39, 42, 45, 48, 51, 53, 56. This theory of deception is implausible for two independent reasons.

First, plaintiffs' alleged ignorance of the presence of ubiquitous heavy metals in food is implausible as a matter of law, since it is directly contradicted by the allegations in the FACC. The FACC readily acknowledges the existence of widespread, general public knowledge, information, and research regarding heavy metals in food and baby food, as well as specific disclosures regarding heavy metals on Plum's website. Specifically, plaintiffs reference and cite the many "reports and articles that identified the presence of Heavy Metals, perchlorate, and/or other undesirable toxins or contaminants in their Baby Foods" going back years. Additionally, those same reports make it clear that it was publicly known that the same heavy metals that exist in packaged food bought in the market exist in food grown in peoples' home gardens. FACC ¶ 195. For example, the well-publicized data points relied on in the FACC include:[8]

[8] In addition to this list, the FACC cites to scientific articles and FDA pronouncements stating the alleged harms of exposure to heavy metals going back many years. FACC at ¶¶ 101, nn. 31-32; 106 ("the knowledge of the risks associated with exposure to heavy metals is not a new phenomenon"); 109, n.40; 122, nn.54-55; 141, n.69; 156 & n.82 ("as a result of public health efforts, exposure to lead has consistently and notably decreased over the past 40 years. These efforts include increasing awareness of the dangers of even low levels of lead exposure to young children."); 163-164.

- In 2011, Consumer Reports published an article entitled "Consumer Reports tests juices for arsenic and lead," which noted the presence of arsenic and lead in apple and grape juice, which a "poll of parents confirms are a mainstay of many children's diets." Borders Decl., Ex. J (cited in Borders Decl., Ex. A at 17).
- In 2017, the Environmental Defense Fund ("EDF") released a report entitled "Lead in food: A hidden health threat," which claimed that 20% of 2,164 baby food samples tested by the FDA from 2003 to 2013 contained lead, and went on to list the most common sources of lead including various fruit juices, sweet potatoes, carrots, teething biscuits and cookies. Borders Decl., Ex. G.
- In 2018, Consumer Reports published an article entitled "Heavy Metals in Baby Food: What You Need to Know." FACC ¶ 195, n.97; Borders Decl., Ex. H. In this article, Consumer Reports analyzed baby and toddler foods for arsenic, lead, cadmium, and mercury. Borders Decl., Ex. H. Consumer Reports also purportedly sent its testing results to different companies that then did their own follow-up investigation, with at least one company responding that it was "reviewing our protocols for further improvement." *Id.* at 12.
- In 2019, the University of Miami, the Clean Label Project, and Ellipse Analytics "published an article describing their study on lead and cadmium in baby food products." FACC at ¶ 195.
- Also in 2019, in a source cited frequently in the FACC, Healthy Babies Bright Futures ("HBBF") published a report regarding the presence of heavy metals in baby food products. FACC ¶ 10 n.5; Borders Decl., Ex. A. In this report, HBBF noted that "[a] number of baby food companies are setting *their own* standards in the absence of enforceable federal limits or guidance" and accordingly, "packaged baby foods may be increasingly likely to have *lower amounts* of heavy metals than homemade varieties." Borders Decl., Ex. A at 3 (emphasis added). HBBF claimed that its report "demonstrat[ed] that tests on over 150 foods . . . found that 95% of the products tested had detectable levels of heavy metals." *Id.*

Similarly, plaintiffs admit that Plum published on its website a set of "FAQs" in which Plum states "Heavy metals are present throughout the environment, including soil and water. Whether you are growing your own produce in your backyard, buying fresh produce from a farmer's market or purchasing a product in the supermarket, these substances will be present in the food to some extent." *See* FACC ¶¶ 88; 82. Indeed, plaintiffs concede, "organic products are just as likely to contain Heavy Metals as non-organic products." *Id*. at ¶ 117. By these allegations, plaintiffs acknowledge that consumers are aware of the realities of food production and know that food products may contain trace residues of heavy metals, herbicides, and pesticides. *See, e.g.*, FACC ¶¶ 10 n.5; 82; 88; 94-138; 141 n.69; 150-156 & n.82; 163-167; 195.

In the Ninth Circuit, these allegations are dispositive because plaintiffs in false advertising cases are held to the common knowledge, experience, and sense that the reasonable consumer brings to the shopping process. *See Moore v. Trader Joe's Co.*, 4 F.4th 874, 882 (9th Cir. 2021) (dismissal of complaint affirmed because reasonable consumer would not be deceived by ambiguous label as alleged; "court [should] consider[] other [non-product-label] information readily available to the consumer that could easily resolve the alleged ambiguity"); *McGee*, 982 F.3d at 707-708 (consumers just know that trans fat comes from partially hydrogenated oil and that trans fat is not healthy). Accordingly, it is not plausible that plaintiffs were blithely ignorant of the possibility that trace amounts of heavy metals or other alleged contaminants are in baby food absent a specific label disclosure. FACC ¶ 30 (emphasis added); *see also* ¶¶ 33, 36, 39, 42, 45, 48, 51, 53, 56.

Second, courts routinely find that because trace contaminants are ubiquitous in the food supply, their mere presence (or possibility of their presence) does not state a claim because it is "not likely to affect consumers' decisions in purchasing the product and is thus not material." *Parks v. Ainsworth Pet Nutrition, LLC*, 377 F. Supp. 3d 241, 248 (S.D.N.Y. 2020); *see also Parks v. Ainsworth Pet Nutrition, LLC*, 2020 WL 832863, at *1 (S.D.N.Y. Feb. 20, 2020) ("The level of glyphosate in the tested Products is negligible and significantly lower than the FDA's limit, which supports a finding that the Products' glyphosate residue is not likely to affect consumer choice"); *Herrington*, 2010 WL 3448531, at *8 (dismissing omission claims regarding

trace amounts of formaldehyde and dioxane for failure to allege facts showing that omissions were material to reasonable consumers); *In re Gen. Mills Glyphosate Litig.*, 2017 WL 2983877, at *5 (D. Minn. July 12, 2017) (not plausible that a reasonable consumer would be deceived by trace glyphosate in food product); *Axon v. Citrus World, Inc.*, 354 F. Supp. 3d 170, 183 (E.D.N.Y. 2018), aff'd sub nom. *Axon v. Florida's Nat. Growers, Inc.*, 813 F. App'x 701 (2d Cir. 2020) ("Given the widespread use of herbicides, the court finds it 'implausible that a reasonable consumer would believe that a product labeled ['Florida's Natural'] could not contain a trace amount of glyphosate that is far below the amount' deemed tolerable by the FDA.") (alteration in original) (citation omitted) (affirming district court's grant of a motion to dismiss); *Tran v. Sioux Honey Ass'n*, 2020 WL 3989444, at *4-5 (C.D. Cal. July 13, 2020) (no evidence reasonable consumers are deceived by the presence of trace amounts of glyphosate); *Gibson v. Quaker Oats Co.*, 2017 WL 3508724, at *4 (N.D. Ill. Aug. 14, 2017) (dismissing claims based on the alleged presence of glyphosate as preempted); *Yu v. Dr Pepper Snapple Grp.*, 2019 WL 2515919, at *3 (N.D. Cal. June 18, 2019) (reasonable consumer would not understand "Natural" to mean the utter absence of residual pesticides, which are well below allowable tolerances).

FDA has confirmed that the levels of heavy metals contained in food are safe and that baby food, including the Plum baby food challenged here, is not adulterated. Borders Decl., Ex. D at 2; Ex. E at 4. This record, combined with the above holdings, compels two dispositive conclusions: (i) consumers know and understand that trace amounts of heavy metals and other alleged contaminants in food products are ubiquitous, *and* (ii) absent allegations that the levels contained in the challenged products exceed FDA levels or render the products adulterated, the mere presence of heavy metals is not material to reasonable consumers. Accordingly, plaintiffs' consumer deception claims should be dismissed on this independent basis.

E. Plaintiffs' Breach Of Implied Warranty Claim Fails

A breach of the implied warranty of merchantability requires that the challenged product is defective or not fit for the ordinary purpose for which the product is used. *See, e.g.*, *Hauter v. Zogarts*, 14 Cal. 3d 104, 117-18 (1975); *Barreto v. Westbrae Nat.*, 2021 WL 76331, at *7 (S.D.N.Y. Jan. 7, 2021); *Sportmart, Inc. v. Spirit Mfg.*, 1999 WL 350662, at *3 (N.D. Ill. May

17, 1999) ("Under the implied warranty of merchantability, goods must be 'fit for the ordinary purposes for which such goods are used.'"); *Dennis v. Whirlpool Corp.*, 2007 WL 9701826, at *6 (S.D. Fla. Mar. 13, 2007) (similar); *Daigle v. Ford Motor Co.*, 713 F. Supp. 2d 822, 826 (D. Minn. 2010) (similar). The implied warranty does not impose a general requirement that goods precisely fulfill the expectation of the buyer. *Stearns v. Select Comfort Retail Corp*., 2009 WL 1635931, at *8 (N.D. Cal. June 5, 2009). "[T]here must be a fundamental defect that renders the product unfit for its ordinary purpose." *Id*. A food product is fit for its ordinary purpose if it is fit for consumption. *See, e.g., Thomas v. Costco Wholesale Corp.*, 2014 WL 5872808, at * 3 (N.D. Cal. Nov. 12, 2014) (for food, an implied warranty claim requires that the product was unsafe to consume); *Barreto*, 2021 WL 76331, at *7.

Plaintiffs have not alleged that Plum's products contain heavy metals in amounts rendering them unsafe for human consumption—the ordinary purpose of baby food. In fact, FDA has expressly stated that packaged baby food is safe to consume, is not adulterated, and that parents should not throw away baby food products or cease feeding them to their children. Because plaintiffs failed to allege that the products are unfit for consumption, the claims must be dismissed. *See Viggiano v. Hansen Nat. Corp.*, 944 F. Supp. 2d 877, 896 (C.D. Cal. 2013); *Bohac v. Gen. Mills, Inc.*, 2014 WL 1266848, at *10 (N.D. Cal. Mar. 26, 2014).

F. Request For Judicial Notice

Plum respectfully requests that the Court take judicial notice of the concurrently-filed Exhibits to the Borders Declaration pursuant to Federal Rule of Evidence 201.

Exhibits A, G through H, and K of the Borders Declaration are judicially noticeable because they are incorporated into the FACC by reference. Plaintiffs cite and rely on Exhibit A in support of their allegations of misrepresentation, which in turn cites to Exhibit K at p.17. *See* FACC at ¶¶ 10, 97, 105, 108, 121, 125, 129, 131, 135, 139, 159, 195, 260. Exhibit H is cited at ¶ 195 n.97 and plaintiffs rely on it in support of their breach of implied warranty claim. Finally, Exhibit G is cited in Exhibit 1 to the FACC, on which plaintiffs heavily rely. FACC at Ex. 1 at p. 22, n.50. The case law is clear that courts may take into consideration documents referenced or relied on in the complaint under the "incorporation by reference" doctrine. *Busey v. P.W.*

Supermarkets, Inc., 368 F. Supp. 2d 1045, 1049 (N.D. Cal. 2005) ("[T]he court may consider a document not attached to the complaint if the complaint specifically refers to it and its authenticity is not questioned.").

Exhibits B through F and I through J of the Borders Declaration consist of documents published by FDA. They are subject to judicial notice because they "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," and are a matter of public record. Fed. R. Evid. 201(b). Courts routinely take judicial notice of public records of government agencies, including public comments and other documents from FDA. *See Riva v. Pepsico, Inc.*, 2015 WL 993350, at *9 n.6 (N.D. Cal. Mar. 4, 2015) (taking judicial notice of "an FDA publication and an FDA presentation that was accessed from the FDA's website"); *Wilson v. Frito-Lay N. Am., Inc.*, 260 F. Supp. 3d 1202, 1207 (N.D. Cal. 2017) ("Courts routinely take judicial notice of similar FDA guidance documents, many of which also appear on FDA's public website").

IV. CONCLUSION

For the foregoing reasons, Plum respectfully requests that the first amended consolidated class action complaint be dismissed with prejudice, or, in the alternative, that the case be dismissed without prejudice or stayed in deference to FDA's primary jurisdiction.

Dated: October 18, 2021

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